

MediPurpose Pte. Ltd.
Special 510(k) - babyLance® Heel Incision Device

510(k) Summary - Revised

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

510(k) Number: K130132
Submitted By: MediPurpose Pte. Ltd.
15 Hoe Chiang Road
#12-02 Tower Fifteen
Singapore, SINGAPORE 089316
Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.
Date Submitted: February 8, 2013
Trade/Proprietary Name: babyLance® Heel Incision Device
Common Name: Infant Heel Lancet
Classification Name: Manual surgical instrument for general use (21 CFR 878.4800)
Class: 1 and Sharps Prevention Feature
Product Code: FMK
Legally Marketed babyLance™ Heel Incision Device, 510(k) # K101417
Predicate Devices:

Device Description:

The MediPurpose babyLance® Heel Incision Device is designed to be a one handed automated incision device for use in heel sticks of newborn and neonatal infants (also called preemie infants). A heel stick is a procedure in which a newborn baby's heel is pricked for blood collection for use in newborn screening tests. The outside plastic casing is designed to be ergonomic for the user and compatible with an infant's foot. The user breaks off the trigger lock from the device, the device is positioned on the newborn's heel and the user depresses the trigger to activate the blade to make an incision. Once the blade has been triggered, the blade is automatically retracted within the housing. The device is discarded in a sharps container after use.

The babyLance® comes in two models, preemie and newborn. The preemie model is to be used on pre term neonates, while the newborn model is for full term neonates. The two models are differentiated by color.

Intended Use:

The babyLance® is an incision device to obtain a blood sample from the heel of newborn and preemie infants. The babyLance® has a sharps prevention feature to protect the user from a sharps injury.

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Similarities and Differences of the Proposed Devices to the Predicate Devices:

Similarities

The modified babyLance® Heel Incision Device (Version 2) has the same basic technology characteristics for an infant heel stick lancet and retains the sharps injury prevention features. It is intended for piercing the heel skin of a preemie or newborn, as the predicate device, and the indications for use are the same. The materials are the same except as noted under differences with the blades using the same medical grade stainless steel and the housings made of the same plastics.

Differences

The modified babyLance® Heel Incision Device (Version 2) outside housing was redesigned with a flat surface against the heel for better stability during the heel stick procedure (*i.e.*, the overall design is now square). The trigger activation was modified with the addition of a spring to prevent the possibility of variable incisions. The added non patient contacting spring is medical grade stainless steel and the trigger plastic was changed to Nylon. All the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

Summary of Testing:

Testing was completed for the sharps prevention feature to the FDA's guidance document, which included product drop tests, cut profiles with comparisons to the predicate device, and simulated use.

Substantial Equivalence Conclusions:

The babyLance® Heel Incision Device has the same principles of operation, intended use, and technological characteristics as the predicate devices. The minor differences do not raise any issues of safety or effectiveness. Testing results support the determination of substantial equivalence with the results demonstrating that the babyLance® Heel Incision Device (Version 2, proposed device) has equivalent or in some cases improved results than the first version of the babyLance Heel Incision Device (predicate device).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medipurpose PTE, Limited
% Regulatory Resources Group, Incorporated
Ms. Julie Stephens
Consultant
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

February 11, 2013

Re: K130132
Trade/Device Name: babyLance® Heel Incision Device
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: FMK
Dated: January 17, 2013
Received: January 22, 2013

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, FOR

Peter  Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130132

Device Name: babyLance® Heel Incision Device

Indications for Use:

The babyLance® is an incision device to obtain a blood sample from the heel of newborn and preemie infants. The babyLance® has a sharps prevention feature to protect the user from a sharps injury.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -S

Digitally signed by Long H. Chen -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Long H. Chen -S,
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Date: 2013.02.08 14:31:59 -05'00'

(Division Sign-off)

Division of Surgical Devices

510(k) Number K130132